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U.S. FOOD & DRUG ADMINISTRATION

August 2, 2019

NxThera (A Boston Scientific Company)
Justin Kapitan
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K191505
Trade/Device Name: Rezum System
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: July 3, 2019
Received: July 5, 2019

Dear Justin Kapitan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Glenn B. Bell, Ph.D.
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191505

Device Name
Rezum System

Indications for Use *(Describe)*
The Rezūm System is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with BPH. It is indicated for men ≥ 50 years of age with a prostate volume ≥ 30cm3 and ≤ 80cm3. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary for the Rezum System

A. Sponsor

NxThera Inc (a wholly-owned indirect subsidiary of Boston Scientific Corporation)
Urology and Women's Health Division
100 Boston Scientific Way
Marlborough, MA 01752

B. Contact

Justin Kapitan
Sr. Regulatory Affairs Specialist
508-683-4518
justin.kapitan@bsci.com

or

Yunus Gulmez
Regulatory Affairs Specialist II
508-683-5320
yunus.gulmez@bsci.com

C. Proposed Device

Trade name:	Rezūm System
Common/usual name:	Vapor Ablation Device
Regulation Number:	21 CFR 876.4300
Regulation Name:	Endoscopic electrosurgical unit and accessories
Classification:	Class II
Product Code:	KNS

D. Predicate Device

Trade name:	Rezūm System
Common/usual name:	Vapor Ablation Device
Regulation Number:	21 CFR 876.4300
Regulation Name:	Endoscopic electrosurgical unit and accessories
Classification:	Class II
Product Code:	KNS

Identification of Predicate Device: NxThera Rezum System, K190093

E. Device(s) Description

The reusable Rezūm Generator is provided with the following reusable components:

- Generator
- One Power Cord

The single-use Rezūm Delivery Device contains the following disposable components:

- One sterile Delivery Device with integrated cable and tubing
- One sterile Syringe
- One sterile Spike Adaptor
- One 50 ml Sterile Water Vial

F. Intended Use/Indications for Use

The Rezūm System is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with BPH. It is indicated for men ≥ 50 years of age with a prostate volume ≥ 30cm^3 and ≤ 80cm^3. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe.

G. Technological Characteristics Compared to Predicate

The principles of operation are identical between the predicate and subject devices: The Rezūm System converts water into vapor outside of the body and the vapor is delivered to the prostate tissue via a needle within the sterile Delivery Device. The water vapor therapy ablates the targeted tissue within the prostate via thermal ablation as energy is transferred from the vapor to the prostate tissue. The amount of vapor delivered is controlled by an RF Generator, which also controls the amount of saline flush used to cool the urethra during the procedure.

The differences between the subject device and the predicate are minor. Specifically, the modifications subject to this submission are limited to updates to the device labeling, change in sterilizer, and change in sterilization cycle. Therefore, the technological characteristics remain equivalent to the predicate device.

H. Substantial Equivalence

The modified NxThera Rezūm System is substantially equivalent to the NxThera Rezūm System (K190093). It has the same intended use for thermal ablation of BPH tissue and the same indications for use. The system design and principles of operation remain the same.

I. Biocompatibility

Biocompatibility testing was performed on the Rezum System (K190093) to show that all patient contacting materials meet applicable biocompatibility standards per **ISO 10993-1:2009** and the FDA guidance: Use of International Standard **ISO 10993-1** "*Biological evaluation of medical devices. Evaluation and testing within a risk management process*." The labeling and sterilization modifications that are the subject of this submission did not affect the materials of the device or the fact that it is biocompatible for its intended use.

J. Performance Testing

The labeling and sterilization modifications to the subject Rezūm System have been evaluated in comparison to the predicate. Based on the change assessment including risk analysis, sterility testing (i.e., lethality and sterilant residual testing) was repeated. The test methods used were equivalent to those submitted for the predicate. Based on the change assessment and risk analsyis all other performance testing was leveraged from the predicate Rezum System (K190093).

The device continues to be sterilized by ethylene oxide (EO) to an SAL 10^{-6} level.

The conclusion of the assessments demonstrates that the modified device continues to function as intended in a manner equivalent to the predicate device. The modified device raises no new issues of safety or effectiveness compared to the predicate.

K. Conclusion

Based on the test data, the same intended use, and same indications for use, the modified Rezūm System is substantially equivalent to its predicate, K190093.